FEB 2 8 2014

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided below.

Device Common Name:	Absorbable Poly (glycolide/L-lactide) Surgical Suture
Device Proprietary Name:	Coated VICRYL* Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture
Submitter:	Ethicon, Inc. Route 22 West P.O. Box 151 Somerville, NJ 08876
Contact:	Peter Cecchini Fellow, Regulatory Affairs 908-218-2457 pcecchin@its.jnj.com
Date Prepared:	February 27, 2014
Classification Regulation:	Suture, Surgical, Absorbable Poly (glycolide/L-lactide) Surgical Suture; 21 CFR §878.4493
Panel:	General and Plastic Surgery Devices
Product Code:	**GAM**
Predicate Device:	Coated VICRYL* Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture (K032420)

Indications for Use:

Coated VICRYL Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

Device Description:

The Coated VICRYL* Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture is a sterile, synthetic absorbable surgical suture (dyed and undyed) and is composed of a copolymer made from 90% glycolide and 10% L-lactide. It is coated with a mixture composed of equal parts of Polyglactin 370 (65%PLA/35%PGA, a copolymer of glycolide and L-lactide) and calcium stearate. A small amount of an antibacterial agent, Irgacare MP** (triclosan), has been added to the suture coating. Irgacare** MP is the tradename given by CIBA Specialty Chemicals Corp. for their high purity material that meets U.S.P. specifications for triclosan. Coated VICRYL*

Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture is a multifilament suture and is available dyed and undyed. It meets U.S.P. requirements, except for diameter, as described in the U.S.P. Monograph for synthetic absorbable surgical suture. The dyed version of the device is available with an approved color additive (D&C Violet No.2). The product is available in U.S.P. sizes 5-0 through 2 in a variety of lengths, with or without needles, and on LIGAPAK* dispensing reels.

The subject device is identical to the predicate device (K032420) in all aspects, including design, materials, sterilization and packaging. The only difference between the proposed and the predicate devices lies in the some labeling statements.

Performance Data:

The technological characteristics of the proposed device are identical to the predicate device, therefore, performance data are not necessary to establish substantial equivalence.

Substantial Equivalence:

The purpose of this 510(k) submission is to obtain a modified indication for use and modified labeling for the Coated VICRYL Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture. A comparison of the proposed and predicate device is provided below.

Substantial Equivalence Comparison Table

	Proposed Device	Predicate Device
510(k) Number	K132580	K032420
Product Code	GAM	GAM
Regulation	21 CFR § 878.4493	21 CFR § 878.4493
Absorbable	Yes	Yes
Characteristics	Same	Coated VICRYL* Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture
Intended use	Same	Indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular, and neurological tissues. Should not be used where extended approximation of tissue under stress is required. Should not be used in patients with known allergic reactions to Irgacare MP**.
How supplied	Same	Sterile, Multifilament strand (braided) Available in a variety of lengths, with or without needles, and on LIGAPAK* dispensing reels. The devices are available in one, two or three dozen boxes.
Color	Same	Undyed or Dyed Suture Strands

	Proposed Device	Predicate Device
Material Composition	Same	Composed of a copolymer made from 90% glycolide and 10% L-lactide. Coated with a mixture composed of equal parts of a copolymer of glycolide and lactide (Polyglactin 370) and Calcium Stearate.
Breaking Strength Retention profile	Same	Approximate percent breaking strength remaining (%BSR) 14 Days -75% 21 Days sizes -50% 28 Days sizes -25%
Absorption profile	Same	Absorption is essentially complete between 56 and 70 days.
USP requirements	Same	Meets USP Monograph -except for diameter
Sterilization	Same	Sterilized by Ethylene Oxide
Packaging	Same	Foil packaging
Antibacterial agent	Same	The suture contains Irgacare MP ** *(triclosan)*, a broad-spectrum antibacterial agent, at no more than 472ug/m.
Labeling	In ACTIONS section: Using zone of inhibition studies, Coated VICRYL Plus Antibacterial Suture has been shown to inhibit colonization of the has been shown to inhibit colonization of the suture by *Staphylococcus aureus*, *Staphylococcus epidermidis, Methicillin Resistant* S. *aureus* . *Methicillin Resistant* S. *epidermidis* and *Escherichia coli* which are microorganisms known to contribute to surgical site infections. Animal studies have demonstrated that VICRYL Plus Antibacterial suture inhibits bacterial colonization of suture after direct in vivo challenge with bacteria. Prospectively planned meta-analyses of randomized clinical trials were performed on the use of suture containing triclosan to lower surgical site infection rates. Examples of such meta-analyses are referenced below [1, 2]. [1]Wang, Z.X., Jiang, C.P., Cao, Y., Ding, Y.T., Systematic review and meta-analysis of triclosan-coated sutures for prevention of surgical site infections., Br. J. Surgery, 2013. [2]Edminston, C.E., Doud, F.C., Leaper, D. Is there an evidence based argument for embracing an antimicrobial (triclosan) - coated suture technology to reduce the risk for surgical site infections? : A meta-analysis. Surgery; 2013; 154; 89-100.	In ACTIONS section: Using zone of inhibition studies, Coated VICRYL Plus Antibacterial Suture has been shown to inhibit colonization of the has been shown to inhibit colonization of the suture by *Staphylococcus aureus*, *Staphylococcus epidermidis, Methicillin Resistant* S. *aureus* . *Methicillin Resistant* S. *epidermidis* and *Escherichia coli* which are microorganisms known to contribute to surgical site infections. Animal studies have demonstrated that VICRYL Plus Antibacterial suture inhibits bacterial colonization of suture after direct in vivo challenge with bacteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Ethicon Incorporated
Mr. Peter Cecchini
Fellow, Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K132580
Trade/Device Name: Coated VICRYL* Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: February 10, 2014
Received: February 11, 2014

Dear Mr. Cecchini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132580

Device Name
Coated VICRYL* Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture

Indications for Use *(Describe)*
Coated VICRYL Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."